Determination of Nonregulated Status for Event 5307 Corn

In response to petition 10-336-01p from Syngenta Biotechnology, Inc. (hereafter referred to as Syngenta), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Event 5307 corn and progeny derived from it are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that Event 5307 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of Event 5307 corn. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for Event 5307 corn and its progeny. Importation of Event 5307 corn seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This determination for Event 5307 corn is based on APHIS' analyses of field and laboratory data submitted by Syngenta, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for Event 5307 corn.

The Plant Pest Risk Assessment conducted on Event 5307 corn concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) agronomic performance evaluations of Event 5307 corn revealed no characteristics that would cause it to be weedier or more difficult to control as weeds than non-genetically engineered corn or any other cultivated corn; (2) gene introgression from Event 5307 corn into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other specialty corn varieties; (3) Based on an evaluation of the gene products and testing of representative non-target species, it has been concluded that Event 5307 corn is unlikely to adversely affect nontarget organisms, including those considered beneficial; (4) horizontal gene transfer is unlikely to occur between Event 5307 corn and organisms with which they cannot interbreed; (5) Event 5307 is engineered to be resistant to the corn rootworm, but is otherwise similar in terms of disease and pest susceptibility to that of its non-genetically engineered corn counterparts and/or other corn cultivars grown in the U.S.

In addition to our finding that Event 5307 corn is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status for Event 5307 corn and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats

(http://www.aphis.usda.gov/biotechnology/not_reg.html). APHIS also concludes in its PPRA that new Event 5307 corn are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for Event 5307 corn, or those observed for other corn varieties not considered regulated articles under 7 CFR part 340. Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status for Event 5307 corn is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

1/29/2013

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date